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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002951024 for a patent by KVINNO CENTRE PTY LTD as filed on 23 August 2002.

WITNESS my hand this
Twenty-second day of August 2003

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ORIGINAL

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: "Anchor and Application Thereof"

The invention is described in the following statement:

"Anchor and Application Thereof"

This invention relates to an anchor which can be used in surgical procedures on both humans and animals.

Background Art

The invention has application to procedures which relates to a method of resolving female incontinence, however the invention is not limited only to such an application. The procedure comprises insertion of a filament which is to be fixed to the ligamentous tissue in order to reconstitute the ligamentary support for the urethra and/or vaginal wall. In the past such filaments have either been fixed to the rectus abdominous muscle or left "tension free" in that muscle.

Disclosure of the Invention

Accordingly the invention resides in a tissue anchor formed of a material which is compatible for location in human and/or animal tissue, said anchor comprising a base, a stem and a head, the base being enlarged and adapted to enable attachment of filamentary material thereto, the stem extending from the base to support the head in spaced relation from the base, said head being of a barbed configuration to enable insertion into muscular and/or facial tissue to prevent dislodgement of the head from the tissue once engaged therewith

According to a preferred feature of the invention the one face of the base is substantially planar and normal to the axis of the stem.

According to a further preferred feature of the invention the other face of the base which is remote from the stem is of a substantially planar configuration.

According to a further preferred feature of the invention, the base is formed with at least one of aperture which is intended to receive the filamentary material.

According to a preferred feature of the invention the base is formed with an aperture configured to receive the filamentary material and to permit slidable movement of the filamentary material through the aperture in one direction but restrict the movement through the aperture in the opposite direction. According to a preferred feature of the invention the aperture is associated with a locking element positioned to extend across the aperture to resiliently clamp the filamentary material between the locking member and the opposed side of the aperture to restrict the movement of the filamentary material in the opposite direction, said locking member adapted to be able to flex away from the opposed side of the aperture to enable movement of the filamentary element in the one direction.

According to a preferred feature of the invention the base is formed as a laminar element having a pair of opposed faces wherein the faces are substantially parallel to the axis of the stem.

According to a further preferred feature of the invention the head comprises an outer portion having a pointed outer end and a plurality of arms which extend from the outer portion in divergent relationship to each other. According to one embodiment the arms are angularly spaced equi-distant around the central axis of the stem.

The invention will be more fully understood in the light of the following description of several specific embodiments

Brief Description of the Drawings

The description is made with reference to the accompanying drawings of which:

Figure 1 is a side elevation of an anchor according to the first embodiment;

Figure 2 is a plan view of the anchor according to the first embodiment;

Figure 3 is an isometric view of the anchor according to the first embodiment;

Figures 4 and 5 are schematic illustrations of the manner of utilisation of the anchor according to the first embodiment;

Figure 6 is an isometric view of an anchor according to the second embodiment;

Figure 7 is a sectional isometric view of the anchor of the second embodiment;

Figure 8 is a side elevation of an insertion tool intended for use with the anchor of the second embodiment;

Figure 9 is an enlarged isometric view of the end of the insertion tool supporting an anchor according to the second embodiment.

Detailed Description of Specific Embodiment

Each of the embodiments are directed to an anchor which can be utilised in association with a filamentary material to enable the fixing and location of the filamentary material into the muscular or ligamentous tissue of a patient. An example of an application of the embodiment relates to a procedure which relates to the location of a filamentary element into the body of a patient for the purposes of resolving female incontinence by replacing at least some ligamentary support for the urethra and/or vaginal wall. It is the function of the anchor according to the embodiment to enable fixing of the filamentary material into the muscular tissue. An alternative function is for the anchor to directly shorten a stretched ligament by inserting the head into one end of the ligament and pushing it backwards into the substance of the ligament to shorten the ligament by creation of a "pleat" within the ligament wall.

The anchor according to the first embodiment as shown at Figures 1, 2 and 3 comprises a base 13, a stem 14 which extends from one face 15 of the base 13 and a head 17 which is supported in spaced relation from the base 13 by the stem 14. The base is of a generally circular sectional configuration and the one face 15 of the base 13 is substantially planar while the other face 17 of the base which is remote from the stem 14 is substantially parallel to the one face 15 and

thus is also substantially planar. The base is formed with a set of apertures 21 which are spaced angularly equi-distant around the central axis of the base.

The head 17 comprises an outer portion 23 which has a pointed conical configuration. In addition the head 17 further comprises a set of arms 25 which extend rearwardly from the outer portion 23 in a divergent relationship to each other to give the head a barbed configuration. The arms 25 are spaced angularly equi-distant around the central axis of the stem 14 and each of the arms are of a generally tapered configuration with their outer ends being more convergent than the main portion of each arm 25.

In use the anchor 17 of the first embodiment is intended to be attached to a length of the filamentary material 27 and the filamentary material is inserted into the body of a patient through utilisation of an insertion tube 29 which as illustrated schematically at Figures 4 and 5. The insertion tube slidably accommodates a tubular plunger 31 which is provided at its outer end with a handle 33. The internal bore of the insertion tube is large enough to receive the anchor 11 while the inner end of the plunger 31 is dimensioned to engage the remote face 19 of the base. A suitable biasing means is provided between the handle 33 and the outer end of the insertion tube to bias the plunger to its outermost position with respect to the insertion tube.

In use the filamentary material 27 is initially passed through the plunger 31 from the handle end to the inner end and the free end of the filamentary material 27 which passes from the inner end of the plunger has an anchor 11 fixed to it. The insertion tube 29 is then inserted into the body cavity through an opening in the body wall such that the free end of the insertion tube is located against the opposed surface of a layer of muscle tissue shown schematically at 35. With the application of an inward axial force on the handle of the plunger, the inner end of the plunger will bear on the base of the anchor and the anchor is caused pass into the muscular or ligamentous tissue 31 to become lodged therein. Because of the pointed configuration of the outer portion 23 of the head the anchor will readily move into engagement with the tissue, however because of the divergent

nature of the arms 25 dislodgement of the anchor from the tissue is restricted. Once the anchor is firmly in position the insertion tube 29 can be removed from the body to leave the filament 27 in place.

The anchor according to the second embodiment as shown at Figures 6 to 9 comprises a base 113, a stem 114 which extends from the base 113 and a head 117 which is supported in spaced relation from the base 113 by the stem 114. The base is of a generally laminar configuration wherein the major faces of the base are substantially planar and parallel to the stem 114. The base is formed with an aperture 121 which extends between the faces and which is associated with a locking member 141 which extends from one side of the aperture to terminate closely adjacent the other side where the spacing between the other side of the aperture and the locking member is less than the thickness of the filamentary material with which the anchor is to be used. The anchor is formed integrally of a suitable plastics material and the junction of the locking member with the one side of the aperture is such that the locking member can flex laterally out of the aperture in one direction but is resistant to movement out of the aperture in the other direction. This selective flexing of the locking member is achieved by forming the face of the locking member 141 which faces the one direction with a recess 143 which has a boundary adjacent the junction. In addition the edge of the locking member 141 in the region adjacent the other side of the aperture is formed with a set of teeth 145 which are divergent outwardly from the edge in the direction of the one direction. The function of the selective flexing of the locking member 141 and the teeth 145 is to permit the filamentary material to be able to be pulled through the space between the locking member and the one side of the aperture in the one direction and to prevent movement of the filamentary material through the same space in the other direction.

The head 117 of the second embodiment comprises an outer portion 123 which has a pointed conical configuration. In addition the head 117 further comprises a set of arms 125 which extend rearwardly from the outer portion 123 in a divergent relationship to each other to give the head a barbed configuration. The

arms 125 are spaced angularly equi-distant around the central axis of the stem 114 and each of the arms are of a generally tapered configuration with their outer ends being more convergent than the main portion of each arm 125.

In use the anchor 117 of the second embodiment is intended to be attached to a length of the filamentary material (not shown) and the filamentary material is inserted into the body of a patient through utilisation of an insertion tube 129 which as illustrated at Figures 8 and 9. The insertion tube slidably accommodates a tubular body 131 which is provided at one end with a handle 133 and at the other end with a cradle-like support 135. The cradle-like support 135 is configured to receive the base of the anchor 110 of the second embodiment and support the anchor as shown at Figure 9. The internal bore of the insertion tube slidably supports a plunger 137 which extends from the one end of the tubular body and is provided with an enlarged head 139. The other end of the plunger terminates closely adjacent the cradle-like support 135. A suitable biasing means is provided between the tubular body 131 and the plunger 137 to bias the plunger to its outermost position with respect to the tubular body 131.

In use the anchor 110 is located in the cradle-like support 135 of the insertion tube and the filamentary material (not shown) is initially passed through the aperture of the anchor. The insertion tube 129 is then inserted into the body cavity through an opening in the body wall such that the free end of the insertion tube with the anchor located thereon is located against the surface of a layer of muscle tissue. With the application of an inward axial force on the enlarged head 139 of the plunger 137, the anchor 110 is caused to pass into the muscular and/or ligamentous tissue to become lodged therein. Because of the pointed configuration of the outer portion 23 of the head, the anchor 110 will readily move into engagement with the tissue, however because of the divergent nature of the arms 125, dislodgement of the anchor from the tissue is restricted. Once the anchor is firmly in position the insertion tube 129 can be removed from the body to leave the anchor and filament 127 in place. Because the filamentary material is only capable of movement through the aperture of the anchor in only one

direction the length of the filamentary material supported from the anchor can be varied and where the filamentary material is used to provide a sling-like support between two anchors supported at spaced positions in the body the spacing between the anchors can be varied and the tension can be varied.

Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

It should be appreciated that the scope of the invention need not be limited to the particular scope of the embodiment described above and in particular is not restricted to the particular example of application of the embodiment described above.

Dated this twenty third day of August 2002.

Kvinno Centre Pty Ltd
Applicant

Wray & Associates
Perth, Western Australia
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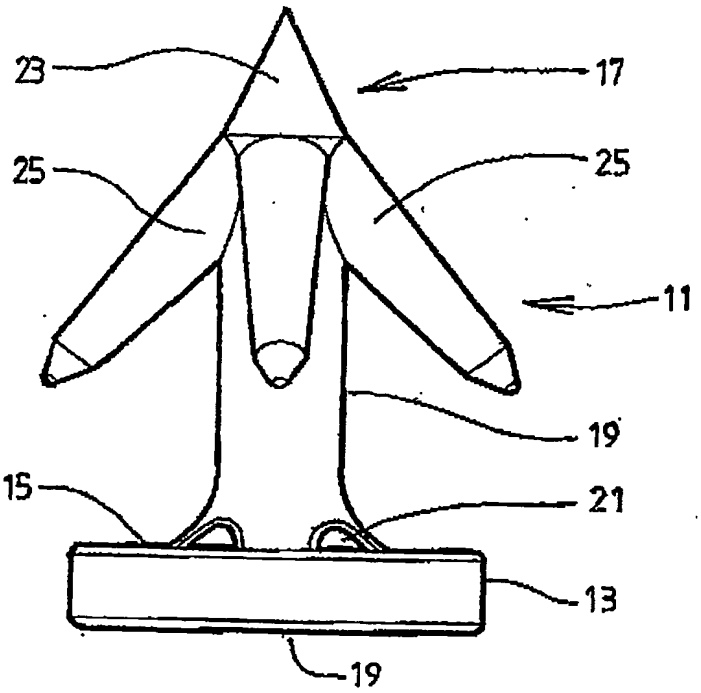
Fig 1



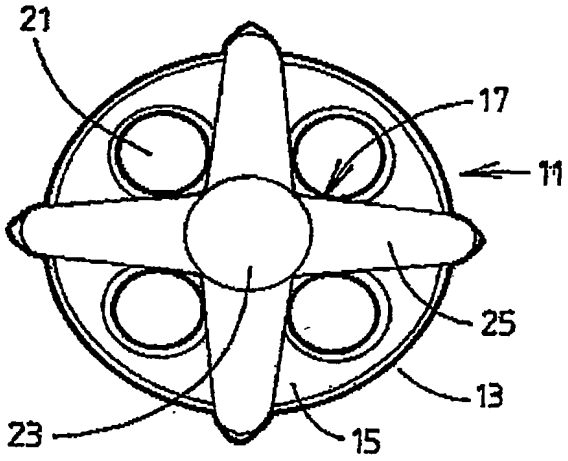
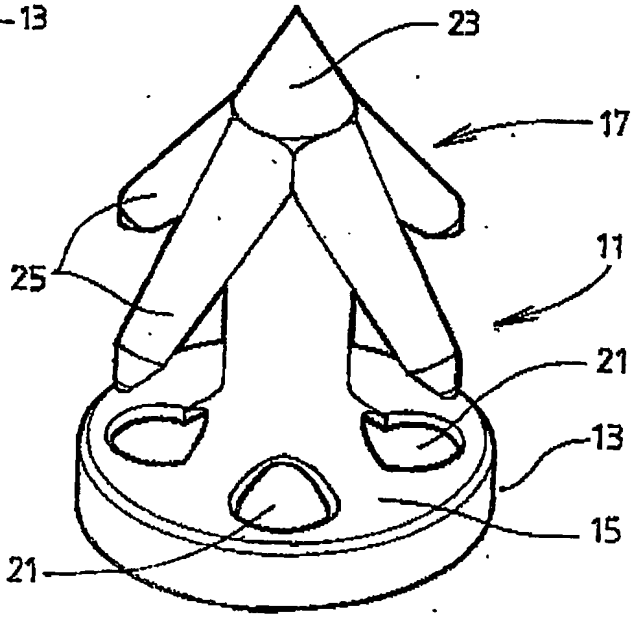


Fig 2

Fig 3



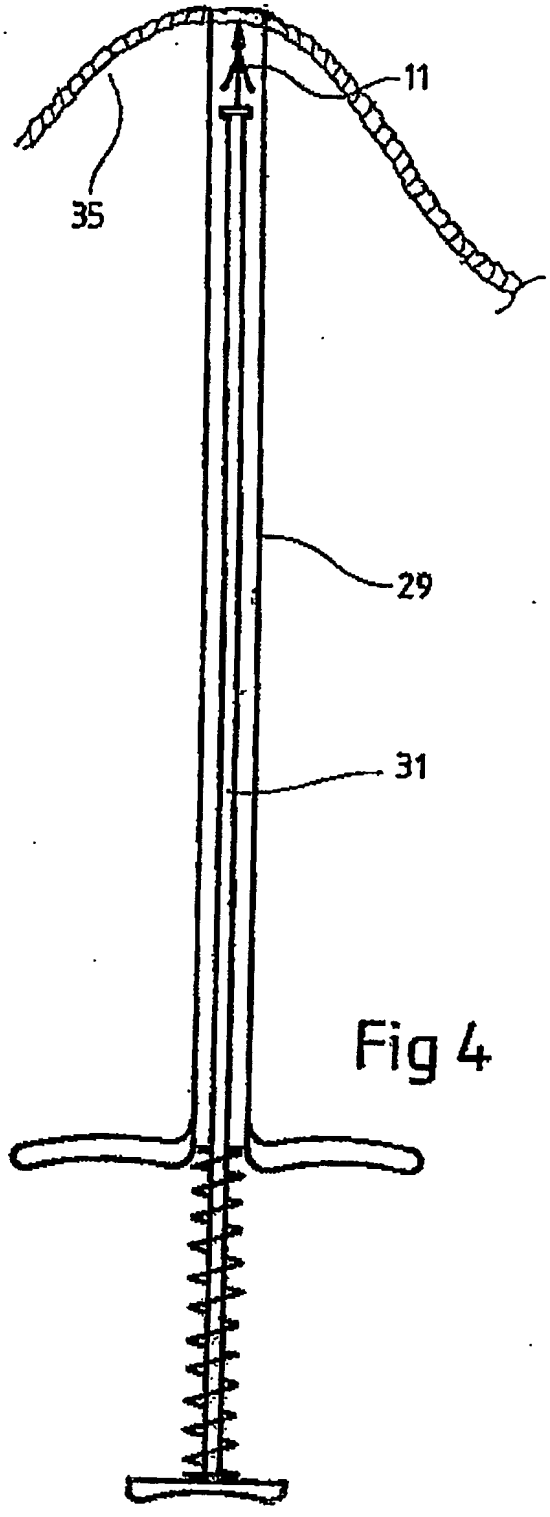


Fig 4

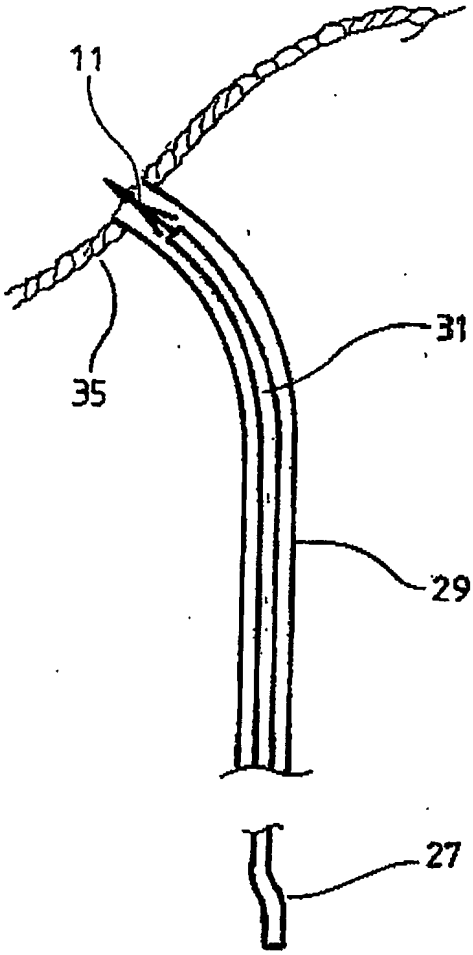


Fig 5

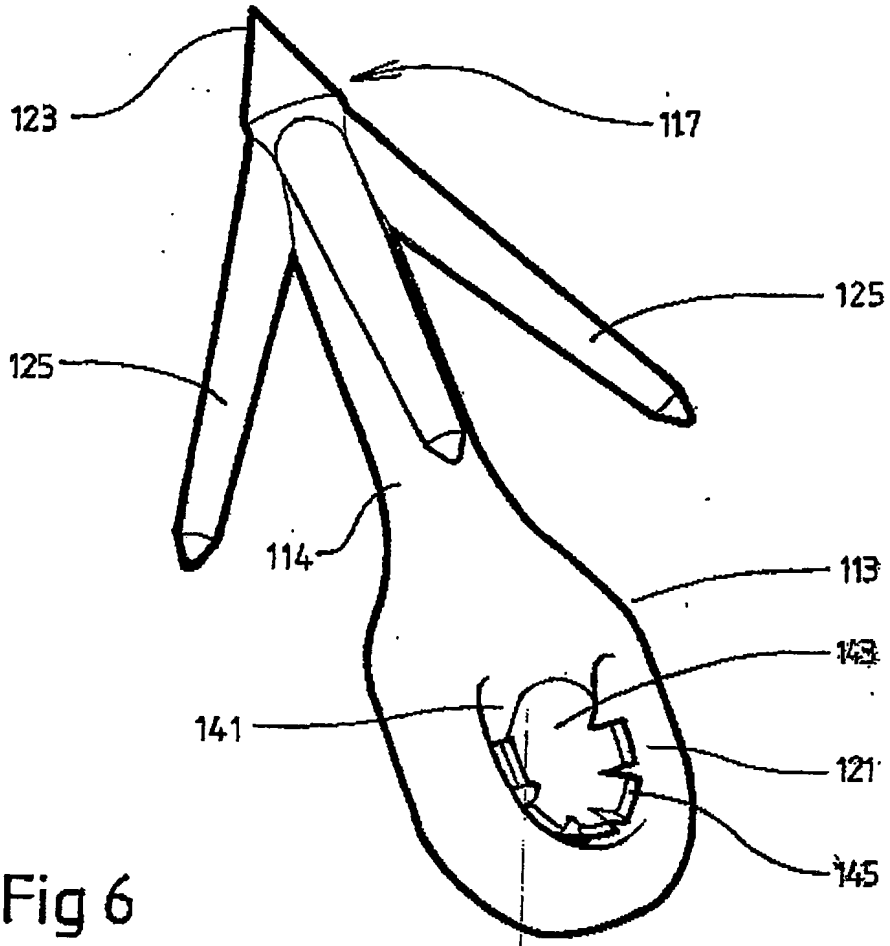


Fig 6

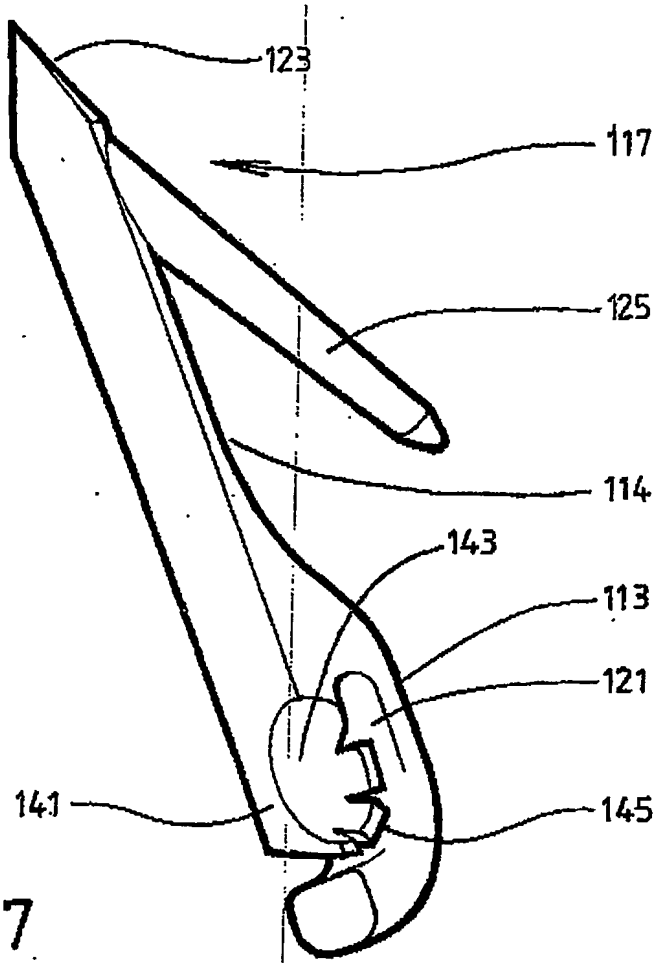


Fig 7

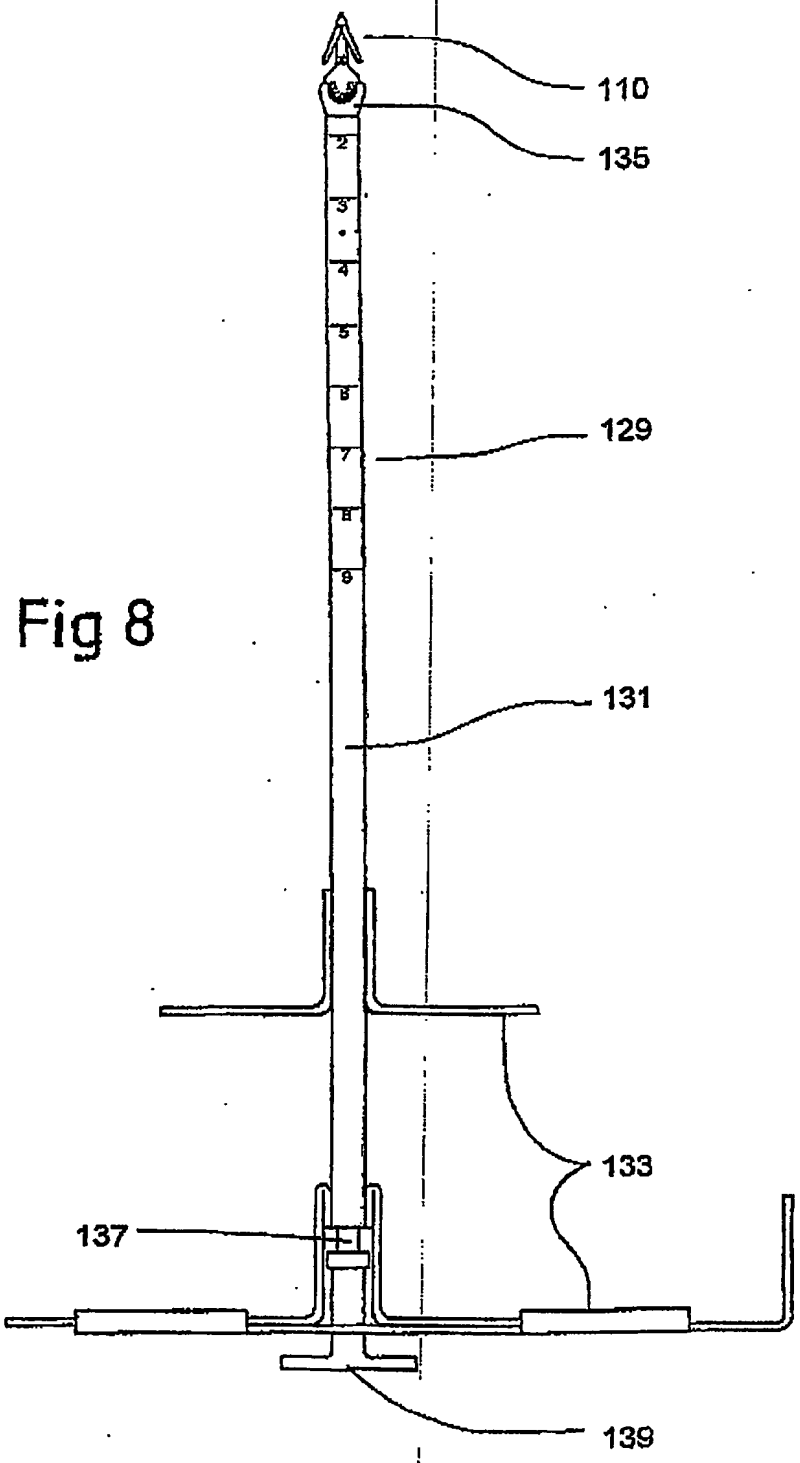


Fig 8

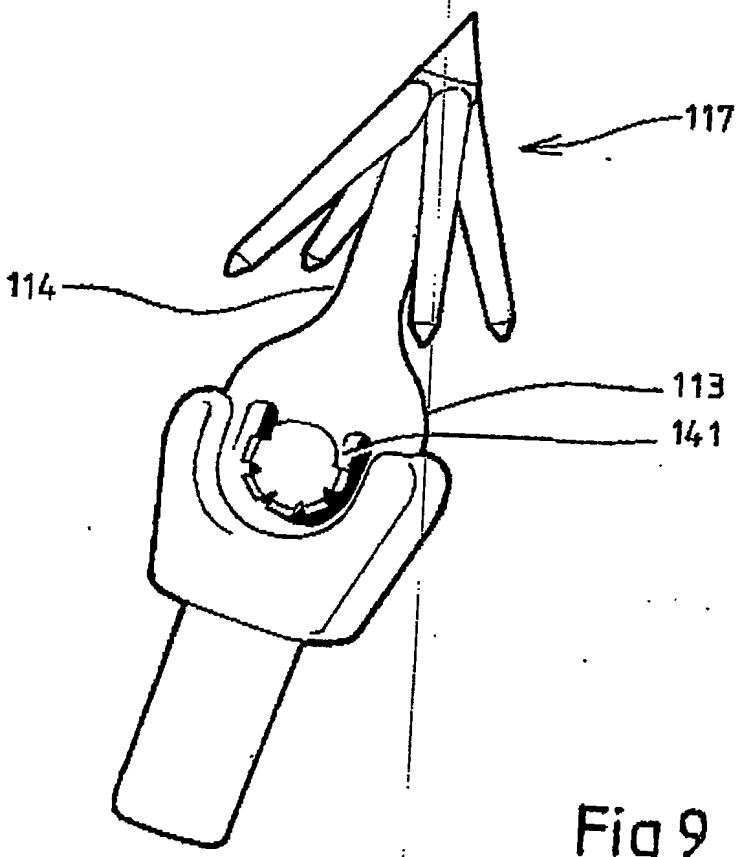


Fig 9